REMARKS/ARGUMENTS

The Invention

The present invention is directed toward a medical implantable device, and more particularly, to a vascular occlusive device, such as an embolic coil, for occluding an aneurysm. The device includes a bioactive coating which is placed on the occlusive device, which preferably takes the form of a helical wound embolic coil, for reacting with bodily tissue in order to promote a desired effect such as, for example, promoting an increase of tissue ingrowth into the occlusive device. In order to prevent an immediate reaction between the bioactive coating and bodily fluids, such as blood, an outer barrier is placed over the bioactive coating and serves to prevent such reaction until the outer barrier is activated, such as by a physician, by applying an external agent to the outer barrier.

The Cited References

The U.S. Patent No. 5,366,454 to Currie, et al. discloses a medication dispensing device for placing within the human body which includes a plurality of compartments each of which contain a dose of medicine to be dispensed. A rupturable membrane is used to seal the opening of each compartment. The membranes have a predetermined elastic defamation limit and a predetermined rupture point. A piezoelectric transducer is used to apply additional stress sufficient to exceed the stress limit of the membrane in order to rupture the membrane. Accordingly, when the piezoelectric transducer is energized by an electrical signal the transducer applies stress to the membrane to cause the membrane to rupture thereby permitting bodily fluids to enter the compartment and mix with the medicine contained within the compartment. It is important to appreciate that this device serves to dispense medication when the membrane is ruptured by applying electrical power to a piezoelectric transducer.

U.S. Patent No. 5,980,550 to Eder, et al., discloses a vascular occlusive device having a bioactive inner coating and a water soluble outer coating. When this device is implanted within the vasculature of the body, the water soluble outer coating comes into contact with bodily fluid, such as blood, and then automatically dissolves to permit contact between the bodily fluid and the inner bioactive agent. With a water soluble outer coating, there is no control by a physician over the point in time at which the outer coating begins to dissolve and so there is no control over the time in which the bodily fluid comes into contact with the bioactive agent. The present invention seeks to overcome this problem which occurs with the device shown in the '550 patent by including a system by which the outer coating may be activated when desired by a physician as opposed to uncontrolled activation of the device.

The U.S. Published Patent Application No. US 2002/0058640 to Abrams, et al., discloses a composition performing a biologically active occlusion within a cavity which includes a biodegradable, polymeric occlusion forming component and a biologically active component which forms an occlusive mass when introduced into the anatomical cavity.

The U.S. Patent No. 6,602,269 to Wallace, et al., discloses a vascular occlusive device which comprises a polymeric material and a liquid agent capable of at least partially solvating the polymeric material.

The U.S. Patent No. 6,773,429 to Sheppard, Jr., et al, discloses a device for enhancing corrosion of an electrode in a biocompatible fluid. It is not clear how this reference is relevant to the subject invention.

Finally, U.S. Patent No. 6,024,754 to Engelson, discloses a vascular occlusive device having a polymeric coating which may be reformed, or solidified, using light, heat, RF or the like to form a rigid mass within the vessel.

The Rejection/Arguments

At the outset, it is noted that the claims of this patent application have been rejected under six different combinations of references incorporating six different U.S. patents and/or a published patent application. It appears that no single claim was rejected by two of the combinations of references. Several of the rejections require the combination of three references in order to reject the claims. It would seem that the Examiner has put together a collection of various references, each of which purportedly teach at least one of the features of the present invention and, upon having Applicants' invention available, has combined these various six references in an attempt to reject the claims of this application. In order to combine references, there must be some teaching or suggestion that the references may be so combined to reject Applicants' claimed invention. Some of the references do not even pertain to the field of vascular occlusion devices.

More particularly, Claims 1, 4, 5, 14, 19, 21, 23 and 24 have been rejected "under 35 U.S.C. 102(b) as being anticipated by Currie et al. ('454)." As described under the heading "The Cited References" the Currie reference discloses a medication dispensing device in which a "rupturable" membrane is placed across several compartments. A piezoelectric transducer is in contact with the rupturable membrane such that when an electrical current is applied to the piezoelectric transducer the transducer adds additional stress to the membrane to thereby rupture the membrane. There is no suggestion that a barrier coating dissolves to uncover a bioactive coating upon application of an external agent. For example, Claim 1 and its dependent Claims 2 through 16 and Claim 14 and its dependent Claims 15 through 18 specifically recite a vasculature occlusive device which includes a bioactive agent and an outer barrier disposed on

the bioactive agent in which the outer barrier exhibits the characteristic of being substantially inert to bodily fluid but dissolving when exposed to an external agent. Clearly, there is no suggestion in the Currie, et al. reference of an "outer barrier exhibiting the characteristic of being substantially inert to bodily fluid but dissolving when exposed to an external agent." This structural limitation is an important limitation in these claims and cannot be simply ignored.

There is extensive discussion in the Currie, et al. reference as to the rupturing membrane associated with each compartment and how this membrane is placed in a stress-inducing manner in order to maintain the membranes in a stressed condition to the elastic defamation limit. There is also extensive discussion as to how the piezoelectric transducer which, in response to an electrical signal, applies additional stress to the membranes sufficient to exceed the rupture point of the membrane. Again, there is no suggestion or teaching in this reference of "an outer barrier exhibiting the characteristic of being substantially inert to bodily fluid but dissolving when exposed to an external agent." Clearly, the Currie, et al. reference is not anticipatory in the sense of 35 U.S.C. 102(b), and it would not be obvious to modify this device to arrive at a device similar to Applicants' claimed invention.

Claim 21, Claim 24 and its dependent Claim 25 have been amended to positively recite that the external agent takes the form of a fluid. Claim 23 has been amended to positively recite that the activating element is a non-electrical element which is supplied to said outer barrier. Currie, et al., discloses a transducer which is electrically activated in order to rupture the covering on the medical dispersing device. With these amendments, these claims now even more clearly distinguish over the Currie, et al. reference.

Claims 2, 3, 6, 7, 10 through 13, 20, 22 and 25 have been rejected "under 35 U.S.C. 103(a) as being unpatentable over Currie et al. ('454) in view of Eder ('550)." As discussed

above, there is no suggestion or teaching in this reference of an "outer barrier exhibiting the characteristic of being substantially inert to bodily fluid but dissolving when exposed to an external agent." The Eder reference does nothing to overcome this shortcoming of Currie, et al. in that the outer coating disclosed by Eder is "a water soluble" outer coating. It should be appreciated that when the vasculature occlusive device as disclosed by Eder, et al. is placed within, for example an aneurysm, the water soluble outer coating begins to dissolve upon contact with blood thereby uncovering the bioactive inner coating. With the present invention, the outer barrier "exhibits the characteristic of being substantially inert to bodily fluid" and remains intact over the bioactive inner layer until such time as an external agent, such as dimethyl sulfoxide, is applied by a physician. With the present invention, the physician is able to determine the time when the outer barrier is to be removed such that there is no contact between blood and the bioactive coating until the physician decides to activate the device. In a device of the type shown by Eder, the physician has no control over the removal of the outer protective barrier. Accordingly, even if the Eder reference could be combined with the Currie, et al. reference, there is no suggestion or teaching of Applicants' claimed invention.

Claim 8 has been rejected "under 35 U.S.C. 103(a) as being unpatentable over Currie et al. ('454) and Eder ('550) in view of Abrams et al (US2002/0058640)." As previously discussed, Currie et al. and Eder do not disclose a vascular occlusive device having a bioactive agent and an outer barrier in which the "outer barrier exhibits the characteristic of being substantially inert to bodily fluid but dissolving when exposed to an external agent." Abrams, et al., discloses polyglycolic acid and ethylene vinyl alcohol, however, this reference also fails to overcome these shortcomings of Currie, et al. and Eder.

Claim 9 has been rejected "under 35 U.S.C. 103(a) as being unpatentable over Currie, et al. ('454) and Eder ('550) in view of Wallace ('269)." Wallace also fails to overcome the shortcomings of Currie et al. and Eder. Again, there is no teaching or suggestion in these references of "an outer barrier exhibiting the characteristic of being substantially inert to bodily fluid but dissolving when exposed to an external agent."

The Examiner has rejected Claims 15 through 18 "under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al ('429) in view of Engelson ('754)." The Examiner has conceded that "Sheppard fails to disclose neither that the support member is a vascular occlusive embolic coil nor that the bioactive takes the form of a thrombus inducing coating." Again, these are important structural limitations of Claims 15 through 18. While Engelson discloses an embolic coil to be placed in an aneurysm, it is not seen how it would be possible to combine the embolic coil of Engelson with the microchip drug delivery system disclosed by Sheppard, et al. There is no teaching or suggestion in these references as to how one would combine these devices which are used for entirely different purposes, i.e. vascular occlusion and release of medication.

Claims 26 and 27 have been rejected "under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al ('429) in view of Wallace et al ('914)." Again, it is not seen how a device for sealing or repairing aneurysms would be combined with a device for releasing medicine in order to arrive at the method steps described and claimed in Clams 26 and 27. The device disclosed by Sheppard serves to release drugs or similar devices and the device disclosed by Wallace, et al. serves the function of sealing an aneurysm. Where is the teaching that one would modify the drug delivery device by shaping it into an embolic coil for use in an aneurysm? Also, where in

these references is the method step of "applying said external agent through the catheter and into the aneurysm to thereby activate said barrier to expose said bioactive agent to bodily tissue... "?

This method step is an important limitation in these claims and may not be simply ignored. The structural limitations, as positively recited in Claims 1 through 25, form an important part of the claimed invention. Similarly, the method steps as positively recited in Claims 26 and 27 form important parts of the claimed method.

With the amendments to Claims 21, 23 and 24 it is believed that all of the claims in this application, i.e. Claims 1 through 27, clearly defined patentable invention over the references of record. Accordingly, it is respectfully submitted that this application is now in condition for allowance and notification of such action is respectfully solicited.

Respectfully submitted,

By: _____
Henry W. Collins
Reg. No. 25,039

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(786) 313-2707
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